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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,335	07/03/2003	Walter A. Zohmann	10012.7	5090

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EXAMINER	
CAMPBELL, VICTORIA P	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,335	ZOHMANN, WALTER A.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action following the third Request for Continued Examination based on the 10/613335 application filed July 3, 2003. Claims 1-12 as amended in the response filed May 19, 2010 are currently pending and considered below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5, 7, and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Regarding the above claims, applicant is relying upon Page 8, lines 14-15 to support the new claim limitation of "spaced at intervals within two millimeters of each other" and "spaced within one millimeter of each other". However, there is insufficient support for this limitation in the specification as filed. The specification as filed reads "Fenestrations 20 are preferably located *within one to two millimeters* [...] of each other for this purpose." The examiner notes that the phrase "within one to two millimeters" is equivalent to stating "*between* one and two millimeters" of each other. Therefore, applicant lacks antecedent basis for the claimed range "within two millimeters" because

that claimed range is equivalent to stating "from zero to two millimeters" and applicant does not have antecedent basis for the range of zero to one millimeter. Furthermore, the phrase "within one millimeter" is equivalent to "from zero to one millimeter", which, as stated above, the applicant does not have antecedent basis for in the specification as filed. Contrary to the statements made in applicant's arguments, the claims still contain the above limitations and as such the rejection under 35 U.S.C. 112, first paragraph, has been maintained.

4. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner notes that the new limitation of independent claims 1, 5, and 7 which requires that the device be "structured to allow location of all of the fenestrations within a fascial compartment during injection" is not supported in the specification or drawings as filed. In fact, Figure 2 as filed and described appears to disclose the opposite, that many of the fenestrations of the needle may actually lay outside the fascial compartment (30) and within the muscular tissue (32 and 34).

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. Applicant has indicated the difficulty of pinpointing the immediate area surrounding a peripheral nerve (Page 3, lines 9-10). Applicant has also indicated that fenestrated portion of their device is capable of being inserted completely within a fascial compartment surrounding a peripheral nerve. However, applicant provides no information on how one is able to accomplish the above task without damage to the peripheral nerve, and appears to only disclose how one can insert the device such that a portion of the fenestrations lie within the fascial compartment, with additional fenestrations lying within the surrounding muscle tissue.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 2, 7-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,250,035 to Smith et al in view of USPGPub 2002/0123723 to Sorenson et al.

Regarding the above claims, Smith et al teach a hollow needle (28), a needle hub (32) having a hollow interior (38) at the proximate end of the hollow needle (34), and a stylet cap (60) on a proximal end of a stylet (68), the stylet being freely movable within the needle (Col. 4, lines 43-45), wherein the stylet cap creates a releasably secure fit with the needle hub (66 received into 38). Smith et al also teach the process of identifying the dermal area of the patient (Col. 3, lines 27-29), inserting and advancing the needle into the dermal area (Col. 4, lines 63-67), withdrawing the stylet (Col. 5, lines 6-8), and injecting an anesthetic (Col. 4, lines 58-60), wherein the needle further comprises a needle hub (32), and wherein withdrawal of the stylet comprising observing a backflow of fluid (Col. 5, lines 8-15).

Smith et al fail to teach or disclose the hollow needle having a plurality of fenestrations longitudinally disposed along alternate sides of the needle, spaced at intervals within two millimeters of each other or one millimeter of each other. However, Sorenson et al teach a plurality of fenestrations (85) disposed on alternate sides of the needle (Fig. 1) at the distal delivery portion of the device (50). Regarding the spacing of the fenestrations, the examiner notes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to space the fenestrations within two millimeters of each other since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable

ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, the examiner notes that the drawings can not be relied upon to show that the fenestrations are more than 5 mm apart because drawings, unless noted, are not treated as drawn to scale and therefore the spacing may be smaller or larger than depicted in the figures of Sorenson et al. Additionally, the examiner notes that the two millimeter spacing could also be around the circumference of the needle, and that it could also be possible for the fenestrations of Sorenson et al to fall within two millimeters of one another in that direction.

Furthermore, although Smith et al do not explicitly disclose inserting the needle through the fascial member, locating at least once of the fenestrations within the fascial compartment, and being structured to allow location of all the fenestrations within a fascial compartment, the examiner notes that the device of Smith et al is capable of performing the advancement step as described in the claims, and therefore it would have been obvious to attempt the method of injection in a fascial compartment with the device of Smith et al and Sorenson et al as described above. Further, the examiner notes that the structural capability of a device to be placed completely within a fascial compartment of any animal is a matter of size and scale, both of which are a matter of design choice in order that the device best serve the patient.

Smith et al and Sorenson et al are analogous art because they are from the same field of endeavor/problem solving area of medical needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Smith et al and Sorenson et al before him or her to modify the needle of

Smith et al to include the multiple distally located apertures of Sorenson et al because doing so provides a wider distribution of fluid than with a single opening while still limiting distribution to a treatment site (Sorenson et al, Paragraphs [0033] and [0036]). Therefore, it would have been obvious to combine Smith et al with Sorenson et al to obtain the invention in the instant claims.

9. Claims 3-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al and Sorenson et al in further view of USPGPub 2002/055715 to Young et al.

Regarding claims 3 and 4, Smith et al and Sorenson et al disclose the invention of claims 1 and 2 as described above, but fail to teach or disclose a fenestration indicator or a magnifying window on the needle hub. However, Young et al teach a needle hub (10) containing both a fenestration indicator (16) and a magnifier (17).

Regarding claims 5 and 6, Smith et al teach a hollow needle (28) being bounded by an occluded tip (72), a needle hub (32) at the proximate end of the hollow needle (34), and a stylet cap (60) on a proximal end of a stylet (68), wherein the stylet cap creates a releasably secure fit with the needle hub (66 received into 38), the stylet being freely movable within the needle (Col. 4, lines 43-45), wherein the stylet occludes the fenestrations (Fig. 11).

Smith et al fail to teach the needle having a plurality of longitudinally disposed fenestrations. Smith et al also fail to teach the needle hub having at least one fenestration indicator and a magnifying window.

Sorenson et al teach a plurality of fenestrations (85) disposed on alternate sides of the needle (Fig. 1). Combination of Smith et al and Sorenson et al is reasoned above.

Young et al teach a needle hub (10) containing both a fenestration indicator (16) and a magnifier (17).

Smith et al, Sorenson et al, and Young et al are analogous art because they are from the same field of endeavor/problem solving area of medical needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Smith et al, Sorenson et al, and Young et al before him or her to modify the needle system of Smith et al and Sorenson et al to include the fenestration indicator and magnifying window of Young et al because the indicator allows the user to properly orient the hub during low light conditions (Young et al, Paragraph [0031]) and the magnifier decreases the recognition time from when the fluid first enters the hub (Young et al, Abstract). Therefore, it would have been obvious to combine Smith et al and Sorenson et al with Young et al to obtain the invention in the instant claims.

Regarding claim 11, please see the rejection above regarding claims 10 and 12.

Response to Arguments

10. Applicant's arguments filed May 19, 2010 have been fully considered but they are not persuasive.

11. In response to applicant's argument that Smith and Sorenson are used for very different purposes from that of the instant invention, the examiner notes that a recitation

of the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Regardless of the intended use of the prior art, if the structure is capable of performing the intended use of the instant application, then it meets the claim. In this case the examiner notes that the devices of Smith and Sorenson, in combination, are capable of performing the functions set forth in applicant's claims.

12. In response to applicant's arguments regarding the spacing of the fenestrations of Sorenson et al, the examiner draws applicant's attention to where this limitation was addressed in the rejection above for explanation.

13. Regarding applicant's suggestion that, because neither of the cited references specifically state the treatment of a fascial compartment, it would not have been obvious to one having ordinary skill in the art to use the device of the combination of Smith and Sorenson to treat a peripheral nerve located in a fascial compartment, the examiner disagrees. At the time of invention, it would have been obvious to one having ordinary skill in the art to try a device such as that formed by the combination of Smith and Sorenson to treat the fascial compartment and the peripheral nerve contained within because the design of such a needle allows for efficient distribution of anesthetic into the tissue.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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